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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 08/475,822   | 06/07/1995  | MARC ALIZON          | 3495.0010-24            | 4214             |
| 22852  | 7590        | 02/13/2004           | EXAMINER                |                  |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER<br>LLP<br>1300 I STREET, NW<br>WASHINGTON, DC 20005 |             |                      | FREDMAN, JEFFREY NORMAN |                  |
|  |             |                      | ART UNIT                | PAPER NUMBER     |
|  |             |                      | 1634                    |                  |

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/475,822

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey Fredman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.129(a)***

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on November 19, 2003 has been entered.

### ***Claim Objections***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires that when new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Here, two claims are numbered "41".

Misnumbered claim 41 been renumbered 42. Specifically, the second claim "41", drawn to the kit of claim 41, was renumbered 42.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application

Art Unit: 1634

being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 35, 37, 39, 41, 43 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

Chang teaches in vitro diagnostic methods for detecting the presence or absence of HIV-1 virus in a biological sample (column 9, lines 25-62) comprising:

contacting said biological sample with a nucleic acid probe of HIV-1 selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

And detecting the formation of hybrids in the biological sample (column 9, lines 25-62).

Chang further teaches the compositions of these nucleic acids (column 9, lines 25-62) as well as HTLV-I and II negative control sequences (column 9, lines 25-62).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region between nucleotides 4000 and 9000 are presented below.

```
Query: 4010  ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4069
              |||
Sbjct: 4197  ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4256
pol      856  I P Y N P Q S Q G V V E S M N K E L K K
```

```
Query: 4070  ttataggacaggtaagagatcaggctgaacatcttaagacagcagtacaaatggcagtat 4129
```

Sbjct: 4257 ttatagggccaggtaagagatcaggctgaacatcttaagacagcagtacaaatggcagtat 4316  
pol 876 I I G Q V R D Q A E H L K T A V Q M A V

```

Query: 4130 tcatccacaatttttaaagaaaannnnnnnnnnnnnnntacagtgcaggggaagaatag 4189
          ||||||||||||||||||||| |||||||||||||||||||
Sbjct: 4317 tcatccacaatttttaaagaaaaggggggattgggggggtacagtgcaggggaagaatag 4376
pol      896  F  I  H  N  F  K  R  K  G  G  I  G  G  Y  S  A  G  E  R  I

```

```

Query: 4190 tagacataatagcaacagacatacaaaactaaagaattacaaaaacaaattacaaaaattc 4249
          |||
Sbjct: 4377 tagacataatagcaacagacatacaaaactaaagaattacaaaaacaaattacaaaaattc 4436
pol      916 V D I I A T D I Q T K E L Q K Q I T K I

```

```

Query: 4250 aaaatttttcgggtttattacagggacagcagaaatccactttggaaaggaccagcaaagc 4309
      |||
Sbjct: 4437 aaaatttttcgggtttattacagggacagcagagatccactttggaaaggaccagcaaagc 4496
pol    936  Q  N  F  R  V  Y  Y  R  D  S  R  D  P  L  W  K  G  P  A  K

```

```

Query: 4310  tcctctggaaaggtgaaggggcagtagtaataacaagataatagtgacataaaagtagtgc 4369
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 4497  tcctctggaaaggtgaaggggcagtagtaataacaagataatagtgacataaaagtagtgc 4556
pol      956  L  L  W  K  G  E  G  A  V  V  I  Q  D  N  S  D  I  K  V  V

```

```

Query: 4370 caagaagaaaagcaaagatcattagggattatggaaaacagatggcaggtgatgattgtg 4429
          |||
Sbjct: 4557 caagaagaaaagcaaagatcattagggattatggaaaacagatggcaggtgatgattgtg 4616
pol      976 P R R K A K I I R D Y G K Q M A G D D C

```

```

Query: 4430 tggcaagtagacagggatgaggattagaacatggaaaagttagtaaaacaccatatgtat 4489
          |||
Sbjct: 4617 tggcaagtagacagggatgaggattagaacatggaaaagttagtaaaacaccatatgtat 4676
pol      996  V  A  S  R  Q  D  E  D  ^^^

```

Query: 4490 gtttcaggggaaagctaggggatggttttatagacatcactatgaaagccctcatccaaga 4549  
 |||  
 Sbjct: 4677 gtttcaggggaaagctaggggatggttttatagacatcactatgaaagccctcatccaaga 4736

Query: 4550 ataagttcagaagtacacatcccactaggggatgctagattggtaataacaacatattgg 4609  
 |||  
 Sbjct: 4737 ataagttcagaagtacacatcccactaggggatgctagattggtaataacaacatattgg 4796

Query: 4610 ggtctgcatacaggagaaagagactggcatattgggtcagggagtcctcatagaatggagg 4669  
 Sbjct: 4797 ggtctgcatacaggagaaagagactggcatctgggtcagggagtcctcatagaatggagg 4856

Art Unit: 1634

Query: 4670 aaaaagagatatagcacacaagtagaccctgaactagcagaccaactaattcatctgtat 4729  
|||||

Sbjct: 4857 aaaaagagatatagcacacaagtagaccctgaactagcagaccaactaattcatctgtat 4916

Query: 4730 tactttgactgtttttcagactctgctataagaaaggccttattaggacacatagtttagc 4789  
|||||

Sbjct: 4917 tactttgactgtttttcagactctgctataagaaaggccttattaggacacatagtttagc 4976

Query: 4790 cctaggtgtgaatatcaagcaggacataacaaggtaggatctctacaatacttggcacta 4849  
|||||

Sbjct: 4977 cctaggtgtgaatatcaagcaggacataacaaggtaggatctctacaatacttggcacta 5036

Query: 4850 gcagcattaataacacccaaaaaagataaagccacctttgcctagtgttacgaaactgaca 4909  
|||||

Sbjct: 5037 gcagcattaataacacccaaaaaagataaagccacctttgcctagtgttacgaaactgaca 5096

Query: 4910 gaggatagatggaacaagccccagaagaccaagggccacagagggagccacacaatgaat 4969  
|||||

Sbjct: 5097 gaggatagatggaacaagccccagaagaccaagggccacagagggagccacacaatgaat 5156

Query: 4970 ggacactagagcttttagaggagcttaagaatgaagctgttagacattttcctaggattt 5029  
|||||

Sbjct: 5157 ggacactagagcttttagaggagcttaagaatgaanctgttagacattttcctaggattt 5216

Query: 5030 ggctccatggccttagggcaacatatctatgaaacttatggggatacttgggcaggagtgg 5089  
|||||

Sbjct: 5217 ggctccatggccttagggcaacatatctatgaaacttatggggatacttgggcaggagtgg 5276

Query: 5090 aagccataataagaattctgcaacaactgctgtttatccattttcagaattgggtgtcga 5149  
|||||

Sbjct: 5277 aagccataataagaattctgcaacaactgntgtttatcca-tttcagaattgggtgtcga 5335

Query: 5150 catagcagaataggcgttactcgacagaggagagcaagaaatggagccagtagatcctag 5209  
|||||

Sbjct: 5336 catagcagaataggcgttactcaacagaggagagcaagaaatggagccagtagatcctag 5395

Query: 5210 actagagccctggaagcatccaggaagtgcgcctaaaactgcttgtaccaattgctattg 5269  
|||||

Sbjct: 5396 actaganccctggaagcatccaggaagtgcgcctaaaactgcttgtaccacttnmtattg 5455

Query: 5270 taaaaagtgttgctttcattgccaaagtttgtttcataacaaaagccttaggcattctccta 5329  
|||||

Art Unit: 1634

Sbjct: 5456 taaaaagtgttgcttttcattgccaaagtttgtttcacaacaaaagccttaggcattctccta 5515  
orfQ 1 C Q V C F T T K A L G I S Y

Query: 5330 tggcaggaagaagcggagacagcgacgaagacctcctcaaggcagtcagactcatcaagt 5389  
||||| |||||||  
Sbjct: 5516 tggcannaagaagcggagacagcgacgaagacctcctcaaggcagtcagactcatcaagt 5575  
orfQ 15 G X K K R R Q R R R P P Q G S Q T H Q V

Query: 5390 ttctctatcaaagcagtaagtagtacatgtaatgcaacctatacaaataagcaatagtagc 5449  
|||||  
Sbjct: 5576 ttctctatcaaagcagtaagtagtacatgtaatgcaacctatacaaataagcaatagcagc 5635  
orfQ 35 S L S K Q ^^^

Query: 5450 attagtagtagcaataataatagcaatagttgtgtggtccatagtaatcatagaatatag 5509  
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Sbjct: 5636 attagtagtagcaataataatagcaatagttgtgtggtccatagtaatcatagaatatag 5695

Query: 5510 gaaaatattaagacaaagaaaaatagacagggttaattgatagactaatagaaagagcaga 5569  
|||||  
Sbjct: 5696 gaaaatattaagacaaagaaaaatagacagggttaattgatagactaatagaaagagcaga 5755  
env 1 K E Q

Query: 5570 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggagat 5629  
|||||  
Sbjct: 5756 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggaaat 5815  
env 4 K T V A M R V K E K Y Q H L W R W G W K

Query: 5630 ggggcaccatgctccttgggatgttgatgatctgtagtgctacagaaaaattgtgggtca 5689  
|||||  
Sbjct: 5816 ggggcaccatgctccttgggatattgatgatctgtagtgctacagaaaaattgtgggtca 5875  
env 24 W G T M L L G I L M I C S A T E K L W V

Query: 5690 cagtctattatggggtacctgtgtggaaggaagcaaccaccactctattttgtgcatcag 5749  
|||||  
Sbjct: 5876 cagtctattatggggtacctgtgtggaaggaagcaaccaccactctattttgtgcatcag 5935  
env 44 T V Y Y G V P V W K E A T T T L F C A S

Query: 5750 atgctaaagcatatgatacagaggtacataatgtttgggccacacatgcctgtgtaccca 5809  
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Sbjct: 5936 atgctaaagcatatgatacagaggtacataatgtttgggccacacatgcctgtgtaccca 5995  
env 64 D A K A Y D T E V H N V W A T H A C V P

Query: 5810 cagaccccaaccacacaagaagtagtattggtaaattgtgacagaaaattttaacatgtgga 5869  
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Sbjct: 5996 cagaccccaaccacacaagaagtagtattggtaaattgtgacagaaaattttaacatgtgga 6055

Art Unit: 1634

env 84 T D P N P Q E V V L V N V T E N F N M W

Query: 5870 aaaatgacatggtagaacagatgcatgaggatataatcagtttatgggatcaaagcctaa 5929

|||||

Sbjct: 6056 aaaatgacatggtagaacagatgcatgaggatataatcagtttatgggatcaaagcctaa 6115

env 104 K N D M V E Q M H E D I I S L W D Q S L

Query: 5930 agccatgtgtaaaattaacccccactctgtgttagtttaaagtgcactgatttgaagaatg 5989

|||||

Sbjct: 6116 agccatgtgtaaaattaacccccactctgtgttagtttaaagtgcactgatttggggaatg 6175

env 124 K P C V K L T P L C V S L K C T D L G N

Query: 5994 taataccaatagtagtagcgaggagaatgataatggagaaaggagagataaaaaactgctc 6053

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Sbjct: 6195 taataccaatagtagtagcgaggagaatgatgatggagaaaggagagataaaaaactgctc 6254

env 151 N T N S S S G E M M M E K G E I K N C S

Query: 6054 tttcaatatcagcacaaagcataagaggttaagggtgcagaaagaatatgcannnnnnnataa 6113

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Sbjct: 6255 tttcaatatcagcacaaagcataagaggttaagggtgcagaaagaatatgcatttttttataa 6314

env 171 F N I S T S I R G K V Q K E Y A F F Y K

Query: 6114 acttgatataataccaatagataatgatactaccagctatacgttgacaagttgtaacac 6173

|||||

Sbjct: 6315 acttgatataataccaatagataatgatactaccagctatacgttgacaagttgtaacac 6374

env 191 L D I I P I D N D T T S Y T L T S C N T

Query: 6174 ctcagtcattacacaggcctgtccaaaggtatcctttgagccaattcccatacattattg 6233

|||||

Sbjct: 6375 ctcagtcattacacaggcctgtccaaaggtatcctttgagccaattcccatacattattg 6434

env 211 S V I T Q A C P K V S F E P I P I H Y C

Query: 6234 tgccccggctgggttttgcgattctaaaatgtaataataagacgttcaatggaacaggacc 6293

|||||

Sbjct: 6435 tgccccggctgggttttgcgattctaaaatgtaataataagacgttcaatggaacaggacc 6494

env 231 A P A G F A I L K C N N K T F N G T G P

Query: 6294 atgtacaaatgtcagcacagtacaatgtacacatggaattaggccagtagtatcaactca 6353

|||||

Sbjct: 6495 atgtacaaatgtcagcacagtacaatgtacacatggaattaggccagtagtatcaactca 6554

env 251 C T N V S T V Q C T H G I R P V V S T Q

Query: 6354 actgctgttaaattggcagctctggcagaagaagaggttagtaattagatctgccaaatttcac 6413

|||||



Art Unit: 1634

Sbjct: 6555 actgctgttgatggcagctctagcagaagaagaggtagtaattagatctgccaatctcac 6614  
env 271 L L L N G S L A E E E V V I R S A N F T

Query: 6414 agacaatgctaaaaccataatagtagcagctgaaccaatctgtagaaattaattgtacaag 6473  
|||||  
Sbjct: 6615 agacaatgctaaaaccataatagtagcagctgaaccaatctgtagaaattaattgtacaag 6674  
env 291 D N A K T I I V Q L N Q S V E I N C T R

Query: 6474 acccaacaacaatacaagaaaaagtatccgtatccagagaggaccagggagagcatttgt 6533  
|||||  
Sbjct: 6675 acccaacaacaatacaagaaaaagtatccgtatccagagaggaccagggagagcatttgt 6734  
env 311 P N N N T R K S I R I Q R G P G R A F V

Query: 6534 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6593  
|||||  
Sbjct: 6735 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6794  
env 331 T I G K I G N M R Q A H C N I S R A K W

Query: 6594 gaataacacttttaaacagatagatagcaaattaagagaacaatttggaataataaaaac 6653  
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Sbjct: 6795 gaatgccacttttaaacagatagctagcaaattaagagaacaatttggaataataaaaac 6854  
env 351 N A T L K Q I A S K L R E Q F G N N K T

Query: 6654 aataatctttaagcagtcctcaggaggggacccagaaattgtaacgcacagttttaattg 6713  
|||||  
Sbjct: 6855 aataatctttaagcaatcctcaggaggggacccagaaattgtaacgcacagttttaattg 6914  
env 371 I I F K Q S S G G D P E I V T H S F N C

Query: 6714 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttggtttaatag 6773  
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Sbjct: 6915 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttggtttaatag 6974  
env 391 G G E F F Y C N S T Q L F N S T W F N S

Query: 6774 tacttgagtagtaaaaggggtcaaataacactgaaggaagtgcacaaatcacctcccatg 6833  
|||||  
Sbjct: 6975 tacttgagtagtaaaaggggtcaaataacactgaaggaagtgcacaaatcacactcccatg 7034  
env 411 T W S T E G S N N T E G S D T I T L P C

Query: 6834 cagaataaaacaaattataaacatgtggcaggaagtaggaaaagcaatgtatgccctcc 6893  
|||||  
Sbjct: 7035 cagaataaaacaaattataaacatgtggcaggaagtaggaaaagcaatgtatgccctcc 7094  
env 431 R I K Q F I N M W Q E V G K A M Y A P P

Query: 6894 catcagtgagcaaaattagatgttcataaatattacagggctgctattaacaagagatgg 6953  
|||||

Art Unit: 1634

Sbjct: 7095 catcagcggacaaattagatgttcatcaaattacagggctgctattaacaagagatgg 7154  
env 451 I S G Q I R C S S N I T G L L L T R D G

Query: 6954 tggtaatagcaacaatgagtcgagatcttcagacctggaggaggagatatgagggacaa 7013  
|||||

Sbjct: 7155 tggtaataacaacaatgggtccgagatcttcagacctggaggaggagatatgagggacaa 7214  
env 471 G N N N N G S E I F R P G G G D M R D N

Query: 7014 ttggagaagtgaattatataaatataaaagtagtaaaaattgaaccattaggagtagcacc 7073  
|||||

Sbjct: 7215 ttggagaagtgaattatataaatataaaagtagtaaaaattgaaccattaggagtagcacc 7274  
env 491 W R S E L Y K Y K V V K I E P L G V A P

Query: 7074 caccaaggcaaagagaagagtggtgcagagagaaaaagagcagtgggaataggagcttt 7133  
|||||

Sbjct: 7275 caccaaggcaaagagaagagtggtgcagagagaaaaagagcagtgggaataggagcttt 7334  
env 511 T K A K R R V V Q R E K R A V G I G A L

Query: 7134 gttccttgggttcttgggagcagcaggaagcactatgggcgacgctcaatgacgctgac 7193  
|||||

Sbjct: 7335 gttccttgggttcttgggagcagcaggaagcactatgggcgacgctcaatgacgctgac 7394  
env 531 F L G F L G A A G S T M G A R S M T L T

Query: 7194 ggtacaggccagacaattattgtctggtatagtgacgagcagacaatttgctgagggc 7253  
|||||

Sbjct: 7395 ggtacaggccagacaattattgtctggtatagtgacgagcagacaatttgctgagggc 7454  
env 551 V Q A R Q L L S G I V Q Q Q N N L L R A

Query: 7254 tattgaggcgcaacagcatctgttgcaactcacagtctggggcatcaagcagctccaggc 7313  
|||||

Sbjct: 7455 tattgaggcgcaacagcatctgttgcaactcacagtctggggcatcaagcagctccaggc 7514  
env 571 I E A Q Q H L L Q L T V W G I K Q L Q A

Query: 7314 aagaatcctggctgtggaaagatacctaaaggatcaacagctcctggggatttgggggttg 7373  
|||||

Sbjct: 7515 aagaatcctggctgtggaaagatacctaaaggatcaacagctcctgggnatttgggggttg 7574  
env 591 R I L A V E R Y L K D Q Q L L G I W G C

Query: 7374 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagttggagtaataaatc 7433  
|||||

Sbjct: 7575 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagttggagtaataaatc 7634  
env 611 S G K L I C T T A V P W N A S W S N K S

Query: 7434 tctggaacagatttggaaataacatgacctggatggagtgggacagagaaattaacaatta 7493  
|||||

Art Unit: 1634

Sbjct: 7635 tctggaacagatttgaataacatgacctggatggagtgggacagagaaattaacaatta 7694  
env 631 L E Q I W N N M T W M E W D R E I N N Y

Query: 7494 cacaagcttaatacactccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7553  
|||||  
Sbjct: 7695 cacaagcttaatacattccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7754  
env 651 T S L I H S L I E E S Q N Q Q E K N E Q

Query: 7554 agaattattggaattagataaatgggcaagtttgtggaattggtttaacataacaaattg 7613  
|||||  
Sbjct: 7755 agaattattggaattagataaatgggcaagtttgtggaattggtttaacataacaaattg 7814  
env 671 E L L E L D K W A S L W N W F N I T N W

Query: 7614 gctgtggtatataaaaattattcataatgatagtaggaggcttggttaggtttaagaatagt 7673  
|||||  
Sbjct: 7815 gctgtggtatataaaaattattcataatgatagtaggaggcttggttaggtttaagaatagt 7874  
env 691 L W Y I K I F I M I V G G L V G L R I V

Query: 7674 ttttgctgtactttctgtagtgaatagagttaggcagggatattcaccattatcgtttca 7733  
|||||  
Sbjct: 7875 ttttgctgtactttctatagtgaatagagttaggcagggatattcaccattatcgtttca 7934  
env 711 F A V L S I V N R V R Q G Y S P L S F Q

Query: 7734 gaccacacctcccaatcccagggggacccgacaggcccggaaggaatagaagaagaaggtgg 7793  
|||||  
Sbjct: 7935 gaccacacctcccaacccccgagggggacccgacaggcccggaaggaatagaagaagaaggtgg 7994  
env 731 T H L P T P R G P D R P E G I E E E G G

Query: 7794 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 7853  
|||||  
Sbjct: 7995 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 8054  
env 751 E R D R D R S I R L V N G S L A L I W D

Query: 7854 cgatctgaggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 7913  
|||||  
Sbjct: 8055 cgatctgaggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 8114  
env 771 D L R S L C L F S Y H R L R D L L L I V

Query: 7914 aacgaggattgtggaacttctgggacgcaggggggtgggaagccctcaaattattggtggaa 7973  
|||||  
Sbjct: 8115 aacgaggattgtggaacttctgggacgcaggggggtgggaagccctcaaattattggtggaa 8174  
env 791 T R I V E L L G R R G W E A L K Y W W N

Query: 7974 tctcctacagtattggagtcaggagctaaagaatagtgcctgtagcttgctcaatgccac 8033  
|||||

Sbjct: 8175 tctcctacagtattggagtcaggaactaaagaatatgtgctgtagcttgctcaatgccac 8234  
 env 811 L L Q Y W S Q E L K N S A V S L L N A T

```
Query:   8034 agctatagcagttagctgaggggacagatatagggttatagaagtagtacaaggagcttatag      8093
           ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Sbjct:  8235 agccatagcagttagctgagggnacagatatagggttatagaagtagtacaaggagcttgtag      8294
env     831    A I A V A E G T D R V I E V V Q G A C R
```

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Query: 8094 agctattcgccacatacctagaagaataagacagggcttggaaaggattttgctataaga 8153
          |||
Sbjct: 8295 agctattcgccacatacctagaagaataagacagggcttggaaaggattttgctataaga 8354
orfF      1                               D R A W K G F C Y K
env      851   A I R H I P R R I R Q G L E R I L L ^^^

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Query:  8154  tgggtggcaagtgggtcaaaaagtagtgtggttggatggcctgctgtaagggaaagaatga 8213
          |||
Sbjct:  8355  tgggtggcaagtgggtcaaaaagtagtgtggttggatggcctactgtaagggaaagaatga 8414
orfF    11  M  G  G  K  W  S  K  S  S  V  V  G  W  P  T  V  R  E  R  M

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Query: 8214  gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctagaaaaacatg 8273
              |||
Sbjct: 8415  gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctggaaaaacatg 8474
orfF   31    R  R  A  E  P  A  A  D  G  V  G  A  A  S  R  D  L  E  K  H

```

Query: 8274 gagcaatcacaagtagcaacacagcagctaacaatgctgattgtgcctggctagaagcac 8333  
 |||  
 Sbjct: 8475 gagcaatcacaagtagcaatacagcagctaccaatgctgcttgtgcctggctagaagcac 8534  
 orfF 51 G A I T S S N T A A T N A A C A W L E A

Query: 8334 aagaggaggaggaggtgggttttccagtcacacctcaggtacctttaagaccaatgactt 8393  
 Sbjct: 8535 aagaggaggaggaggtgggttttccactcacacctcaggtacctttaagaccaatgactt 8594  
 orfF 71 O E E E E V G F P L T P Q V P L R P M T

```

Query: 8394 acaaggcagctgtagatcttagccactttttaaaagaaaaggggggactggaagggctaa 8453
          |||
Sbjct: 8595 acaaggcagctgtagatcttagccactttttaaaagaaaaggggggactggaagggctaa 8654
orfF 91 Y K A A V D L S H F L K E K G G L E G L

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Query: 8454 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8513
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 8655 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8714
orfF 111 I H S Q R R Q D I L D L W I Y H T Q G Y

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Query: 8514 tccctgattagcagaactacacaccagggccagggatcagatatccactgacctttggat 8573

Art Unit: 1634

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      |||
Sbjct: 8715 tccctgattggcagaactacacaccagggccaggggtcagatatccactgacctttggat 8774
orfF 131 F P D W Q N Y T P G P G V R Y P L T F G

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Query: 8574 ggtgctacaagctagtaccagttgagccagagaagttagaagaagccaacaaaggagaga 8633
      |||
Sbjct: 8775 ggtgctacaagctagtaccagttgagccagataaggtagaagaggccaataaaggagaga 8834
orfF 151 W C Y K L V P V E P D K V E E A N K G E

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Query: 8634 acaccagcttgttacaccctgtgagcctgcatggaatggatgacccggagagagaagtgt 8693
      |||
Sbjct: 8835 acaccagcttgttacaccctgtgagcctgcatggaatggatgacccctgagagagaagtgt 8894
orfF 171 N T S L L H P V S L H G M D D P E R E V

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Query: 8694 tagagtggaggtttgacagccgcctagcatttcacatggcccgagagctgcatccgg 8753
      |||
Sbjct: 8895 tagagtggaggtttgacagccgcctagcatttcacatggcccgagagctgcatccgg 8954
orfF 191 L E W R F D S R L A F H H V A R E L H P

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Query: 8754 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 8813
      |||
Sbjct: 8955 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 9014
orfF 211 E Y F K N C ^^^

```

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Query: 8814 cagggaggcgtggcctggcgaggactggggagtggcgagccctcagatcctgcatataag 8873
      |||
Sbjct: 9015 cagggaggcgtggcctggcgaggactggggagtggcgagccctcagatgctgcatataa 9074

```

```

Query: 8874 cagctgctttttgctgtactgggtctctctggttagaccagatctgagcctgggagctc 8933
      |||
Sbjct: 9075 cagctgctttttgctgtactgggtctctctggttagaccagatttgagcctgggagctc 9134

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Score = 2796 bits (1454), Expect = 0.0

Identities = 1477/1489 (99%)

Strand = Plus / Plus

It is noted that with regard to, for example, the sequence region between nucleotides 4487 and 5086 claimed in claim 11, there are two nucleotide differences between the sequences. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that

Art Unit: 1634

was significantly more advanced than that in 1984, when sequencing error rates were likely significantly higher. In the 599 nucleotide sequence which is the first sequence of claim 1, two errors would represent approximately a 0.3% error rate. Thus, these sequences are identical within the error range available and the anticipation rejection is proper.

With regard to the kit claims, it is noted that the preamble phrase "a kit" imposes no structural requirements upon the product claims.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent 6,001,977) as applied to claims 35, 37, 39, 41, 43 and 45 as discussed above and further in view of White et al (U.S. Patent 4,677,054).

Chang teaches the limitations of claims 35, 37, 39, 41, 43 and 45 as discussed above, including detection of HIV-1 using nucleic acid probes by dot blotting.

Chang does not teach the use of labels on the probes.

White teaches labeling probes and hybridization reagents using radioactive labels for detection of nucleic acids including RNA from animal tissue by hybridization (column 2, lines 6-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of White with the method of Change because White states that the method is widely applicable, stating "It will be obvious to those skilled in the art that the method of the present invention is general in scope and can be used for DNA and mRNA-like analysis of all sorts of biological specimens (column 2, lines 40-44)." Further motivation to detect using these methods is provided by White, who notes "Very small amounts of sample can be tested. Furthermore, the samples can be hybridized with multiple probes used in sequence (column 3, lines 2-4)". An ordinary practitioner would have been motivated to use the

labels of White to detect HIV as taught by Chang since White says that the method is broadly applicable, permits the use of small sample amounts and permits detection using multiple different probes to enhance specificity.

### ***Response to Arguments***

9. Applicant's arguments filed November 19, 2003 have been fully considered but they are not persuasive.

Applicant argues that the sequence of Chang was more carefully performed than the raw sequence analysis of Richterich, because the sequence was "polished". This refers to a term of art in which the sequence is repeatedly checked for accuracy. However, the issue in the current case is simply one of fact. Are the sequences the same or not? The examiner has read portions of John Crewdson's book "Science Fictions", which discusses the original studies on HIV in 1984. Crewdson quotes Wong-Staal, a coinventor on the Chang patent, as saying "that LAV and HTLV-3 are independent isolations of the same virus (see page 165)." Crewdson further notes "They had come from the same patient (see page 165)."

Further, Applicant specifically argues that Chang performed careful analysis. This is entirely belied and contradicted by Crewdson, who notes "The gene map of ARV, decoded by Paul Luciw and his California team, was a dead match for LAV, which meant Gallo's map was dead wrong (see page 173)." So contrary to Applicant's arguments, there was not significant care taken by Chang's group. At note s, on page 565, Crewdson writes, "The Gallo group had sequenced two clones of HTLV-3B. The first didn't appear to have the fifth gene but the second did. Or did it? Because HTLV-1



Art Unit: 1634

didn't have five genes, the prevailing opinion in Gallo's lab was that the AIDS virus didn't either and what looked like a fifth gene was an artifact." This further supports erroneous sequencing by Gallo, since at least once they failed to find an entire gene. This would be rather difficult to explain in a careful sequencing project.

So Applicant's entire argument rests on the supposition, without evidence, that the sequences were carefully performed.

Applicant's other argument is that Ratner resequences BH10. This is not correct. In reading Ratner's paper, there is no evidence that Ratner resequenced BH-10. Ratner simply compared a different clone to BH-10. At page 63, bottom of the page, Ratner states "The previously sequenced clone BH10 (28)", referring to reference 28, which is the original 1985 Nature paper and not some later resequencing. So, in fact, Ratner does NOT support applicant's position.

As a final point, it is noted that in this case, there is better evidence than is ordinarily available that the strains sequenced by the two different groups are, in fact, the same since it is clear that the LAI strain is common to both of these applications. There is express evidence, as discussed above, that the viruses were the same.


Since the evidence of record does not support Applicant's position, the rejections are maintained.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey Fredman  
Primary Examiner  
Art Unit 1634